

Overcoming the Patent Gap: A Guide to Patenting for Plastic Surgeons

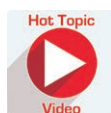
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Background: Patenting protects innovation, fosters academic incentives, promotes competition, and generates new revenue for clinician-inventors and their institutions. Despite these benefits, and despite plastic surgery's history of innovation, plastic surgery-related patent applications are few. The goal of this article was to use unpublished data and formulate a robust discussion.

Methods: The U.S. Patent and Trademark Office's boolean search was investigated between the timeline of 1975 and June 23, 2020, to identify patents related to the key phrases to contrast patent (both, issued and filed) tally in each specialty. Queries for two key phrases related to plastic surgery and a core plastic surgical activity, both with and without the added term "plastic surgery," were performed.

Results: Total patents with "cardiology" outnumber those with "plastic surgery" by 22,450 versus 7749 (i.e., almost 3:1). The overwhelming number of patents with "cosmetic" are non-plastic-surgery related: 87,910 total versus 2782 for those with plastic surgery. The corresponding numbers for "wound healing" are 36,359 versus 2703. Reasons for the patent gap between clinical innovations in plastic surgery and number of patents in our field are identified. Clear steps to bridge this gap are delineated that include a step-by-step process for patenting, from idea creation through commercialization. The authors propose "breakthrough to bank," a framework wherein academic medical centers can create an environment of innovative freedom, establish the infrastructure for technological transfer of intellectual property, and generate a pipeline toward commercial applications.

Conclusions: Innovation and inventions are important hallmarks for the progress of plastic surgery. Using a stepwise process, it may be possible to convert ideas into patents. (*Plast. Reconstr. Surg.* 148: 908, 2021.)

Plastic surgeons have a rich history of innovation,¹ solving difficult clinical problems and developing novel surgical procedures. Nevertheless, despite strong support from national societies^{2,3} and competitive advantages over other subspecialties,⁴ they have a very slim patent portfolio (see Methods and Results section). This gap increases further when comparing plastic surgical identity in patents in core work such as wound healing. We define the patent gap as the gap between innovativeness and patent holding: we identify its causes, demystify the patenting process, and present a stepwise

breakthrough-to-bank method to apply for and market patents.

DEMYSTIFYING THE PATENT PROCESS

What Is a Patent?

A patent is intellectual property that gives its owner the legal right to exclude others from making, using, or selling an invention, which must be new, useful, and nonobvious. A national government or supranational body such as the European

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A "Hot Topic Video" by Editor-in-Chief Rod J. Rohrich, M.D., accompanies this article. Go to PRSJJournal.com and click on "Plastic Surgery Hot Topics" in the "Digital Media" tab to watch.

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Union grants the inventor this right for a limited duration, called the term of the patent (typically lasting 20 years from the filing date), in exchange for publicly disclosing the invention's details. Like any property right, a patent may be sold, licensed, mortgaged, assigned, transferred, given away, or simply abandoned.⁵ In the United States, the U.S. Patent and Trademark Office performs patent processing; its predecessor, the Patent Board, was established in 1790.

Why Patent at All?

Criticisms that patenting in medicine limits progress and is unnecessary or even harmful are untrue. Quoting Abraham Lincoln: "Patents provide the fuel of interest to the fire of genius." As in other fields where patenting is accepted, the financial benefits of medical patents provide incentives to inventors to scale production to global levels, improve product quality, hasten translation from bench-to-bedside, and foster competition (after public disclosure) to advance technology and develop improved products.

An example is penicillin, originally discovered in 1928 by Alexander Fleming, who chose not to patent it⁶; his work stayed obscure until rediscovered by Oxford University's Ernst Chain and Howard Florey at World War II's start. Their collaborator, the U.S. Department of Agriculture's Andrew J. Moyer,⁷ developed a bulk-manufacture process (patent awarded to the U.S. Department of Agriculture in 1948) that enabled penicillin's use in the War. Vigorous commercial competition subsequent to abundant availability of pure penicillin eventually yielded semisynthetic penicillins that resisted stomach-acid degradation (allowing oral administration), destruction by staphylococcal penicillinase, extended spectrum against Gram-negative organisms, or all three, with the original production costs reduced more than 100-fold.

Patent royalties provide income for academic institutions. Synthetic insulin (City of Hope Cancer Center⁸), Gatorade (University of Florida⁹), and vacuum-assisted closure (Baptist Wake Forest¹⁰) have yielded royalties close to \$1 billion. Lastly, clinical inventors can find creative outlets through their patent work, lifting their professional profile through institutional recognition, promotions, awards, and grants.¹¹

Types of Patents

Utility Patent

A new, useful process of manufacturing or a machine, or composition of matter, including a new molecule such as a drug, cosmetic application,

or useful improvement thereof. Ninety percent of all patents are utility patents. Medical utility patents include surgical devices (e.g., retractors, forceps), electronic health records, diagnostic machines, tools, joint-prosthesis, and implants.

Contrary to popular belief, medical/surgical procedures can be patented, not merely trademarked. However, the Medical Procedure Exception to Patent Infringement¹² protects other medical practitioners (including supervised medical students or surgical residents) from infringement claims if they perform the procedure to benefit a patient. However, the Infringement exception does not extend to any patented device that was invented to facilitate the procedure.

Design Patent

A new and original design embodied in or applied to an article of manufacture. Well-known examples include typefaces and fonts, and distinctive shapes, such as the original Coca-Cola bottle (hourglass waist, longitudinal grooves for gripping). Frederic Bartholdi, the Statue of Liberty's sculptor, received a design patent that covered all reproductions, including souvenirs. Company logos can, however, only be trademarked, not patented. Design patents can involve functional improvements (e.g., for prostheses), and even if nonfunctional, support brand recognition by means of distinctive appearance. In some locales, such as the European Union, Japan, and the Republic of Korea, an alternative, simpler mechanism called a registered design achieves the same purpose.

Plant Patent

Plant patents are issued for new and distinct, invented, or discovered asexually reproduced plants. Medicinal plant-based products, especially in cosmeceuticals and nutraceuticals,^{13,14} are relevant to plastic surgery. Plant patents, when used in mixtures of pharmaceutical compounds, may reinforce utility patents.

Trademarks and Copyrights

A trademark is a brand name, a symbol, or logo, that confers brand recognition. Several procedures, such as the K-Lift face lift procedure,¹⁵ are trademarked.

METHODS AND RESULTS

We used the U.S. Patent and Trademark Office's boolean search¹⁶ to identify patents related to the key phrases "plastic surgery" and "cardiology," to contrast patent tally in each specialty. We also queried for two key-phrases related to plastic surgery: "wound healing" and

“cosmetic,” both without and with the added term “plastic surgery.” We searched for all filed patents, not just issued ones.

Figure 1 shows the results, as of June 23, 2020. Total patents with “cardiology” outnumber those with “plastic surgery” by 22,450 versus 7749 (i.e., almost 3:1). The overwhelming number of patents with “cosmetic” are non-plastic-surgery related: 87,910 total versus 2782 with “plastic surgery.” The corresponding numbers for “wound healing” are 36,359 versus 2703.

DISCUSSION

Possible Reasons for the Patent Gap

Valuation Deficit

Clinicians may underestimate their work—even one small advance over existing practice can potentially make it patentable—or may overestimate their work: it may have clinical value but lacks commercial viability.

Strategy Shortfall

Most clinicians fail to address both requirements of successful commercialization: intellectual property protection and commercial interest. Surgeons may also be unaware of the details of the Medical Procedure Exception to Patent Infringement discussed earlier.

Process Deficit and Costs

The arduousness and costs of patent application submission, scrutiny, and analysis before issue, and productizing and supporting the invention after issue, can be frightening. This is especially so for individuals unfamiliar with business-school basics (e.g., finance, accounting, microeconomics, marketing, operations). By omitting rigorous cost versus future-value analysis, clinicians may give up prematurely.

Training Deficit

Although most training programs emphasize publication and research, few if any train their residents on the nuances of converting their innovations into patents.

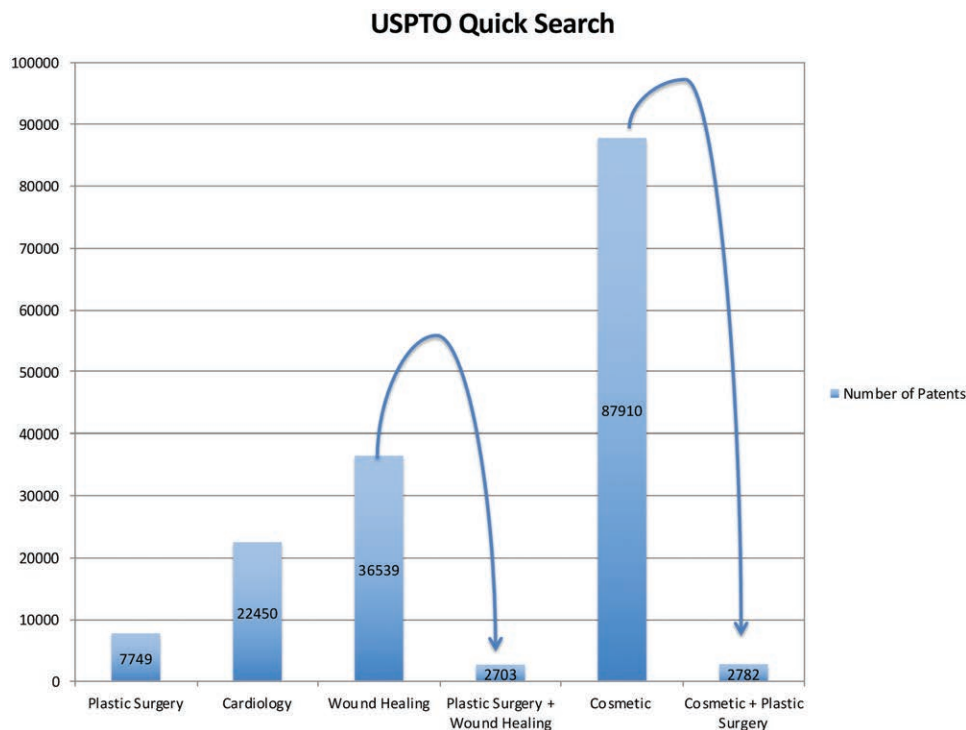


Fig. 1. Quick Search tool of the United States Patent and Trademark Office (USPTO). The term “plastic surgery” searched in “any field” (1976 to July 24, 2020) reveals 7749 patents; one-third that of “cardiology” and one-thirtieth that of “cancer” (230,508). Broadening the terms to describe what plastic surgeons actually do (rather than a general specialty) such as “wound healing” reveals 36,539 patents; however, when the same term “wound healing” is meshed with “plastic surgery” as a description/specification, the number of patents drops precipitously to 2703 (11-fold decrease). Similarly “cosmetic” AND “plastic surgery” barely yielded 2782 patents (32-fold decrease) despite the alarming growth in cosmetic surgery in the past decade.

Prepatenting Requisites That No One Tells You About

First, do not make your invention's details public before filing a patent application: this can destroy novelty.¹⁷ "Public" includes press/journal articles, promotional material provided without express restriction on redistribution, or presentation at conferences open freely to all registrants. The rationale here is that a patent is a quid pro quo: limited monopoly in exchange for disclosing the invention's details publicly. However, if the public already knows the details, or if knowledgeable persons can infer these readily from the released information, the invention becomes "prior art": there is no disclosure to be had. Note that details are different from merely announcing that you have an invention that does something.

In North American countries, the inventor can still file within a 1-year grace period after disclosure. But the European Union and China lack a grace period. Although some disclosure to third parties (e.g., potential investors) is unavoidable, Pheiffer¹⁸ recommends using nondisclosure agreements and limiting disclosure to only potentially vital individuals, or filing before public disclosure. If choosing the latter, do so only if your idea is finalized: the patent's text cannot be revised after filing.

Second, the United States and the European Union follow a "first-to-file" policy, giving priority not to the person who first invented something, but to the person who files first with the patent office. Alexander Graham Bell filed his patent for the telephone approximately 1 day before his

rival Elisha Gray. First-to-file applies only to undisclosed, independently discovered but identical ideas by two or more rival inventors. It does not allow a person to patent another's publicly disclosed but unpatented innovation, which could constitute prior art.

Third, within a particular period after filing (18 months in the United States), a patent application's details become public even if the patent is not yet granted, although the inventor retains legal protections. This allows "peer review" and legal challenges by other inventors if the patent's idea is not original, or if its claims are overly broad. One must anticipate competition in the race to capture the market.

The Patent Process: Breakthrough-to-Bank

A valuable patent is one that provides a return on investment through licensing or product development. Value can be developed through the following steps.

Step 1: Evaluate Eligibility

Investigate the idea using the following tests:

- Test no. 1: Is it new?
- Test no. 2: Is it nonobvious?

Gut impressions on these criteria may be pessimistic or optimistic: patent attorneys can provide deeper insights about what has been accepted or rejected previously. "The Clip," used to seal opened moisture-sensitive-snack bags, was granted a patent even though its inspiration, the

Eligibility Test #3

- **Market:**
 - Interest,
 - Size,
 - Timely Returns
- **Technology:**
 - Comparative Analysis;
 - Stakeholder identification;
 - Partners; Suppliers; Customers.
- **IP Protection:**
 - Must supply the licensee sufficient competitive advantage
 - Return On Investment

Fig. 2. Eligibility test no. 3.

clipboard used to hold paper sheets in place while writing, went back to 1870. Vacuum-assisted closure also survived the nonobviousness test.

Online search of patent databases, notably the U.S. Patent and Trademark Office^{19–21} and Google Patents,^{22,23} is essential. At the U.S. Patent and Trademark Office, patents before 1975 can only be searched by issue patent number, and (manually assigned) current U.S. classification. However, Google Patents, which includes foreign patent applications, has performed optical character recognition on all U.S. patents, and lacks this limitation.

You may use professional researchers or, in academia, law school students. Although patent attorneys almost always have a science, technology, engineering, or medical undergraduate/graduate degree, do not expect them to know plastic surgery. When they identify similar patents, prepare to spend time explaining how your invention differs.

Test no. 3: Is it useful?

What problem does it solve, for which target user? What is the market size? Only approximately one in 5000 granted patents make their inventors any money: some granted patents cover devices such as chastity belts. “What is not worth doing, is worth not doing well” (Ashok R. Shaha, MD, FACS, Head and Neck Surgery and Oncology, Memorial Sloan Kettering Cancer Center, New York, N.Y., personal communication, 2016). An example of how to assess usefulness from clinical and market standpoints is illustrated in [Figures 2 and 3](#).

Test no. 4. Will you own part, or all, of the patent, or does your employer own the invention?

Although by default employees own their inventions’ intellectual property rights, employers

increasingly use employment contracts that claim rights to anything the employee invents, sometimes even inventions completely unrelated to their job. Revenue-sharing policies differ across employers, including academic institutions, and may not always be equitable; written policies may not even exist. Furthermore, if you use the employer’s “resources” (computers, equipment, laboratory, even e-mail), the employer has “shop rights” and can use your invention without paying you, although they cannot sell/license it to third parties.

For self-employed individuals (including independent contractors, the mechanism organizations use to avoid paying benefits to de facto employees), you own the intellectual property even if your work was commissioned by someone else—unless your contract with them explicitly grants them the rights. Other caveats include technology with military or national security risks, which the government may classify because it considers public disclosure hazardous.

For further details, see Stim,²⁴ who suggests that, if you have any negotiating power (as some recruited faculty do), intellectual property attorneys can help you negotiate as narrow an assignment as possible with a potential employer before signing an agreement.

Test no. 5: If self-employed: do you have it in you?

As discussed later under “Estimated Timeline,” the process can be drawn out and emotionally draining; tenacity is key. If the above eligibility tests fail, go back to the drawing board and develop ways to improve on the product. If still not feasible, consider academic and research outlets for the idea (e.g., publications or award submission).

Clinical and Market Analysis

- 100 million patients in a potential market suffer from diabetes.
- 30 million of these suffer complications and require about 3 tests of their HbA1C per year a total of 90 million tests a year.
- Your invention of a test kit that provides a rapid HbA1C testing could potentially capture, based on your market research, 10% of the testing requirement for this population. Hence your market size = 90,000,000 tests multiplied by 10% = 9,000,000 test kits.
- You plan on selling the test kits for \$50.
- If you sold 9,000,000 tests you would generate \$450M in sales.

Fig. 3. Clinical and market analysis. This example illustrates how large the potential of a simple new device could be when applied over a large market.

Breakthrough to Bank

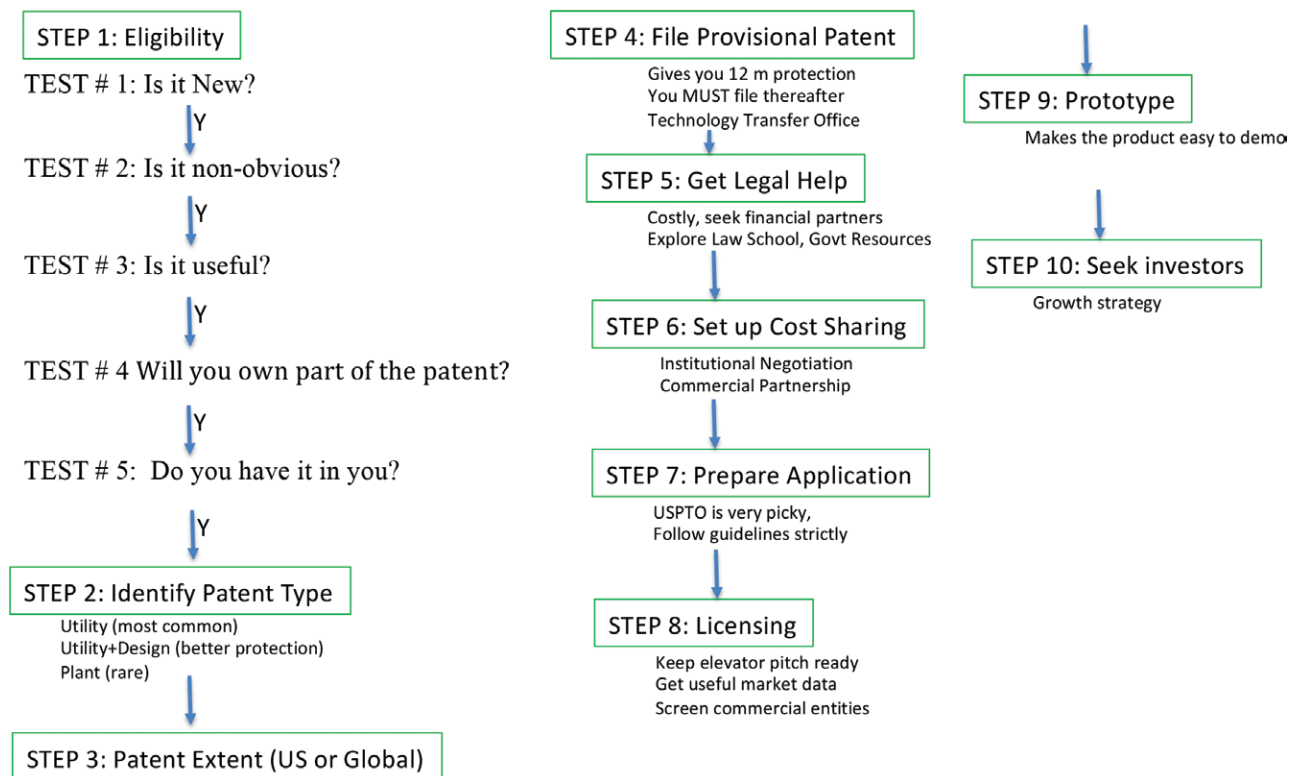


Fig. 4. Breakthrough-to-bank: a 10-step guide for developing an idea into a commercial success. *USPTO*, U.S. Patent and Trademark Office.

Step 2: Identify Patent Type

Ideally, file for both a utility patent (which gives the longest protection) and a design patent (if a device) to best protect all the invention's embodiments. You may also register a trademark to protect the device's brand name, plus a copyright for marketing content. It is important to correctly categorize the invention before patent application (Fig. 4).

Step 3: Determine Patent Extent

Because patent laws vary greatly by country, you will almost invariably require patent law firms to file in multiple countries where you plan to sell the product.

Step 4: Provisional Patent

A U.S. provisional patent allows an inventor to market an invention with the label "patent pending" before a formal patent issue, even before public disclosure. It establishes an effective filing date to forestall later priority-related disputes. However, it is nonrenewable and viable only for 12 months, during which the inventor must file for a nonprovisional patent.

Step 5: Legal Assistance

Highly specialized patent attorneys are invaluable, but costly. If you are in academia, your university's technology transfer office or equivalent may help in various aspects, including bearing most or all filing and legal costs, and connecting with commercial entities for licensing. If the university has a law school, students specializing in intellectual property or patent law may become willing collaborators.

The U.S. Patent and Trademark Office offers an assistance program,²⁵ pro bono help, and special programs for low-income inventors.²⁶ Some law schools conduct legal clinics where supervised law students help people navigate the patent process.²⁷ In the United Kingdom, the Chartered Institute of Patent Attorneys holds regular countrywide Clinics to provide free basic advice to unrepresented innovators.

Step 6: Seed Costs and Cost Sharing

Many universities use innovation-fostering models such as internal seed grants, innovation- and program-development funds, specific project grants, and philanthropy. The U.S. federal

government supports commercialization of scientific and technological advances by means of Small Business Innovative Research and Small Business Technology Transfer Research grant mechanisms. In both, the principal investigator is a small-business owner. However, in the Small Business Technology Transfer Research program, the business develops the invention jointly with a nonprofit organization (e.g., university, federal laboratory), transferring technology from latter to former, and thence to market, with revenue-sharing.²⁸ Both mechanisms involve three progressively higher funded phases where a subsequent-phase award is contingent on meeting the previous phase's goals. In both, the principal investigator must be employed primarily by the business rather than the nonprofit.

For academic inventors, many universities have written policies on how their investment/expenses will be recovered (e.g., taking most or all of the initial profits before sharing royalties with the inventor). These policies also apply if the inventor creates a startup with external partners—such entrepreneurship is often encouraged—and applies for the Small Business Technology Transfer Research program. Because costs add up quickly,²⁹ if such policies do not exist, one must negotiate with the university/employer regarding how to handle these.

Step 7: Patent Application

When filling the application, you must describe the invention type, its innovative advantage, purpose, construction method, building blocks, and how it works. As when writing scientific manuscripts, cite prior art and clarify how your invention is an advance. Drawings and diagrams must show every feature stated in the “claims” section. There are strict requirements for patent drawings regarding the permissible materials, size, form, symbols, and sharing.^{19,30–34} Patent attorneys' inputs are necessary to ensure that the patent's claims are neither too limited (inviting infringement or workarounds) or too broad (inviting challenges).

Once submitted, the U.S. Patent and Trademark Office will determine whether your idea is patent-eligible. If your patent is approved, you will need to pay a fee before it is granted. If rejected, you can appeal the decision, or make amendments to your application materials and submit them again. If your idea is not patentable, you may still have options for legally protecting it. Consider whether having it trademarked, copyrighted, or declared a trade secret is a better option.

Step 8: Prototype and Development of Business Plan

These tasks should commence right after filing. In the commercial world, many commercial products (e.g., Clip and Instant Pot) went into production and achieved brand recognition well before patent issue. Most successful products also go through cycles of prototyping and iterative refinement based on feedback from test customers.

Developing a business plan forces you to determine postissue revenue, market size, potential competitors, and costs, and plan for other tasks involved (e.g., tech support, replacement parts). If you plan to attract external investors, or licensees, a credible business plan convinces them that you have done your homework.

Step 9: Investment and Licensing

Whether you choose to establish a startup to manufacture your invention, or license it to others, capital infusion is necessary: an effective presentation (including the business plan, above) is an essential persuasion tool. For both venture capital and licensing, legal help is invariably necessary to preserve your intellectual property value and rights, which also encompass contracts with employees and independent contractors, and issues such as joint development, terms of use, privacy policies, and distribution agreements. Good legal help also protects you against one-sided or predatory terms (not uncommonly attempted in the biomedicine/technology world).

Expected Timeline

Invention is often the shortest and easiest part of the process: commercial success is delayed by the following hurdles.

The Patenting Process Itself

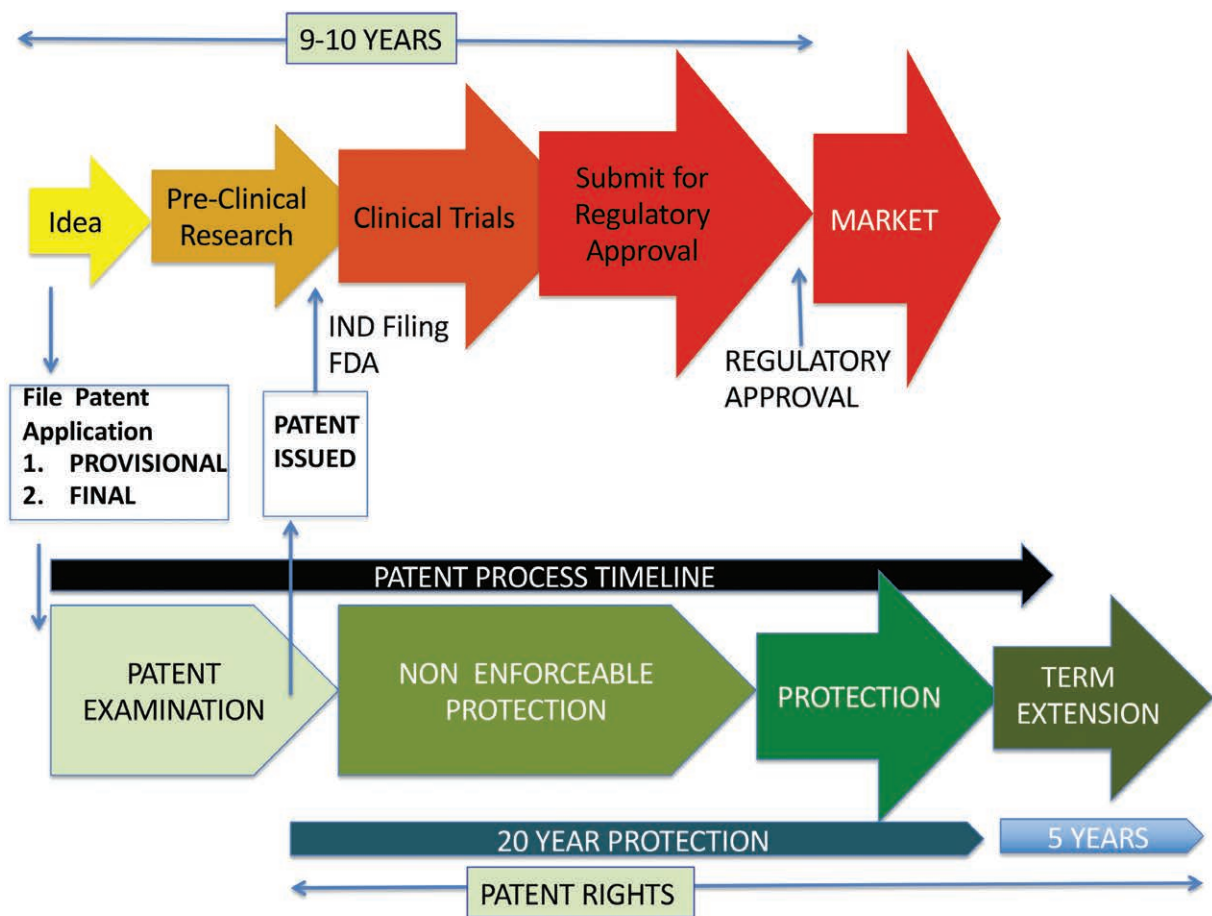
Issuance takes up to 3 years, depending on patent type and rarity of similar claims.

Regulatory Approval of Medications and Trivial Devices

To be patented, a novel molecule or device does not need proof of efficacy or safety (most patented synthetic molecules fail in animal studies). However, inventions that make claims of medical efficacy require U.S. Food and Drug Administration approval. The expense here forces most inventor startups, unless backed by extensive venture capital, to partner with established pharmaceutical/medical device companies.

Peer Approval

The estimated timeline is graphically illustrated here below in [Figure 5, above](#). We must also



Peer Acceptance Timeline

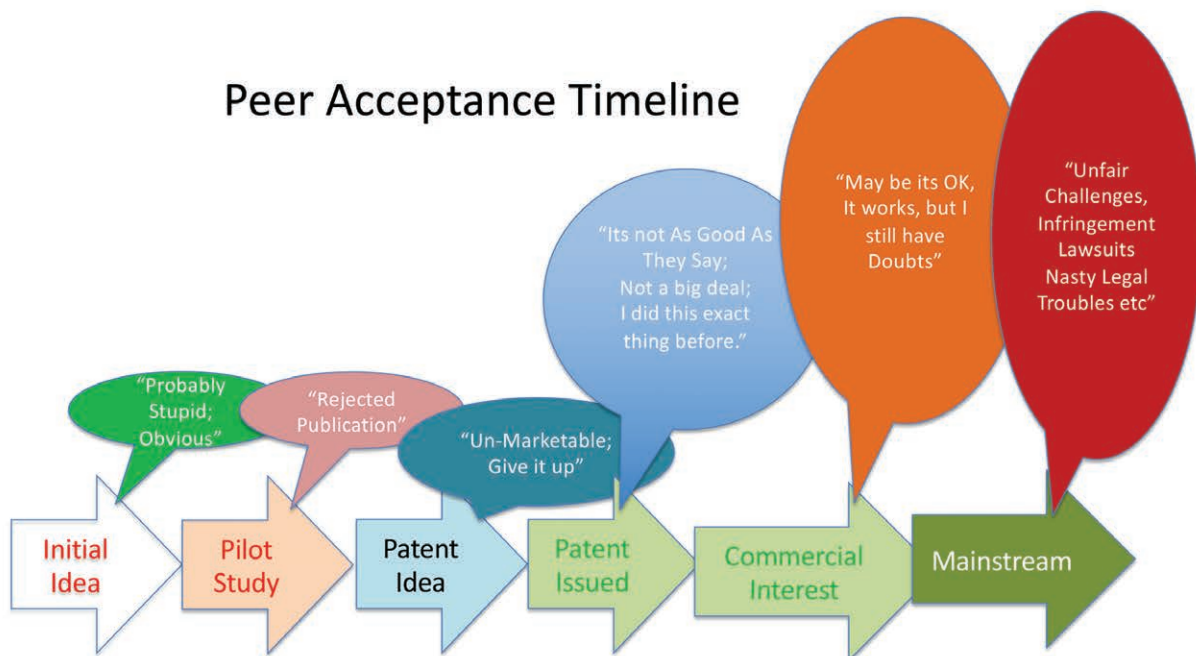


Fig. 5. (Above) Patent timeline. This figure shows the interaction between U.S. Patent and Trademark Office filing and filing for regulatory approval. *IND*, investigational new drug; *FDA*, U.S. Food and Drug Administration. (Below) Peer acceptance timeline.

add here that peers may not be as supportive as you expect. The “peer-acceptance” timeline of your idea as it progresses through the patent process is shown in [Figure 5](#), below.

Reimbursement through Insurance

Although product development costs of must be recouped through pricing, the extortionate pricing of some new therapies has caused blowback, and insurance (including Medicare/Medicaid) may be understandably reluctant to pay for these unless the medical condition addressed is serious and lacks alternative therapy. Correspondingly high patient co-pays also disincentivize routine use.

Litigation: Defending against Infringement and Challenges

Success attracts copycats. Wrzesinski³⁵ points out that, in the United States, patent infringement is often used as a business strategy, because counterlitigation is challenging.

- Typical patent litigation costs between \$1 and 4 million.
- The penalties for both willful infringement and enhanced infringement (three times the estimated damages plus attorney fees) are identical and too modest to be deterrent.
- U.S. patent law does not (and federal courts need not) consider defendants’ intent regarding deliberate versus inadvertent infringement.
- “Willful infringement” lacks an explicit definition applicable to all cases. The opinion in *Read Corp. v Portec Inc.*, often used as a precedent, defined nine factors to identify willfulness. However, documenting having conducted an investigation can easily circumvent some factors, such as “whether the infringer, after discovering patent protection, investigated the patent and formed a good-faith belief that it was invalid, or not infringed.”

The topic of patent challenges would merit an article by itself, with higher courts often overruling lower courts’ decisions. An example is *Association for Molecular Pathology v. Myriad Genetics*, where the U.S. Supreme Court unanimously overruled a federal circuit decision and invalidated Myriad’s patents on the *BRCA1* and *BRCA2* genes, ruling that “A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated.”

CONCLUSIONS

Overcoming the Patent Gap: Advice for Inventors and Department Leaders

Although there are no magic bullets, we believe that the following steps will enhance the number of patent applications and foster innovation.

- Engender curiosity right at the start of resident training, in particular, encouraging tech-savvy and/or entrepreneurial residents.
- Create an environment for discovery by means of mechanisms such as setting up innovation funds, competitive prizes, or clinical/scientific challenges for difficult problems identified at grand rounds, morbidity and morality conferences, or from patent experiences.
- Get away from relative value unit/money-grubbing metrics as clinical-productivity measures. Patentable innovations are more long-term and fulfilling goals than focus on revenue-generation alone.
- Level the playing field. Foster equal participation by clinicians and researchers in applications for research grants and awards.
- Create strong partnerships across departments, colleges, also involving the technology transfer office and, by means of professional organizations, across institutions as well, to emphasize new discovery.
- Create money-back schemes that seed-fund new patent applications until they reach enough maturity to attract external capital.
- For department heads: in the absence of written policies regarding revenue division, negotiate pragmatically with university finance leaders, making clear that if and when the invention generates substantial revenue, your department *must* have a substantial piece too.
- Align legal departments, and the local law school, for patent help.
- Co-support other departments when in need. This creates a groundswell of support for you, when you need it.

Progress in surgery has been fueled by innovation and the development of new ideas, approaches, and techniques. It is now time for our specialty as a whole to take the next step and foster a new generation of inventor-clinicians.

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